REMARKS

Please reconsider the application in view of the amendments made above and the remarks set out below.

- Claims 40-48 are pending. 49-59?
- Claims 60-99 are newly added.

In the paragraph that begins on page 7, line 1, Applicants have amended the specification to include a description of the heparin complex with the tradename DURAFLO. Since this added material is a description of a composition, the recitation of the composition's name in the application, as filed, inherently discloses this material. Therefore, this added material is not new matter. The source of this descriptive material is Richard T. Hummel's thesis, Master of Science in Perfusion Program, Milwaukee School of Engineering, entitled "In Vitro Comparison of Carmeda and DURAFLO II Heparin Bonded Circuits", June 15, 1995, abstract. URL: http://www.msoe.edu/library/perfusion_thesis.shtml

Applicants have deleted claims 37 and 39. Newly added claims 60 and 62 are substantially the same as claims 37 and 49, respectively, before the previous amendment, but Applicants have added the following limitations: (1) the coating increases biocompatibility and hemocompatibility of the blood-contacting surface; and (2) the coating is adapted to deliver therapeutic amounts of therapeutic drugs into the blood wherein therapeutic drugs include heparin or heparin derivatives. Support for claim 60 can be found in claim 37 combined with specification page 5, lines 12-20. Support for claim 62 can be found in claim 49 combined with specification page 5, lines 12-20. The structure of the paragraph at specification page 5, lines 12-20, supports heparin as an example of a drug. The specification does not limit the disclosed drugs to be only heparin. In fact, the specification specifically refers to the "time-release of drug(s)".

Specification page 8, line 27. Clearly, the specification teaches drugs in addition to heparin.

Applicants have added claims 64-99; these are substantially identical to claims 1-32, as originally filed.

In this response, Applicants have reintroduced claims with subject matter previously rejected during this application's prosecution. Where that subject matter re-raises or is likely to re-raise art rejections previously made, but later withdrawn because the previous claims containing that subject matter were cancelled, this response addresses those art rejections in terms of the new claims. Throughout this response as a specific rejection is discussed, it is identified by the Office Action mailing date and the paragraph number in which the rejection was made.

35 U.S.C. § 112 Rejections

In response to the Examiner's rejections set out in the Office Action mailed 24 September 2002, paragraphs 1-8, Applicants have amended the claims and specifications, as indicated above. This renders the rejections under 35 U.S.C. § 112 moot.

35 U.S.C. § 102 claim Rejections

Previously, in the Office Action mailed 18 July 2001, paragraph 9, the Examiner rejected the subject matter of claims 1, 2, 4, and 15-17 under 35 U.S.C. § 102(e) as being anticipated by Zhong, U.S. Patent No. 6,197,051, the 051-patent. That subject matter is encompassed by claims 64 and following.

Zhong teaches a permanently attached bioactive agent. "Because the optional bioactive agents of the present invention are covalently bonded to polycarbonate-polyurethane primer, the bio-active agents are permanently attached to the substrate unlike certain of the transient coatings discussed above." 051-patent, column 3, lines 28-32. claim 64 requires that the bioactive component of the second layer contain releasable heparin compound. Zhong does not teach or suggest this element.

Since Zhong does not teach or suggest each and every element of claim 64, Zhong does not anticipate it. Claims 65-77 depend from claim 64 and contain all of the limitations of claim 64. Therefore, Zhong likewise fails to anticipate claims 65-77.

Previously, in the Office Action mailed 18 July 2001, paragraph 10, the Examiner rejected the subject matter of claims 1, 2, 4, and 5 under 35 U.S.C. § 102(b) as being anticipated by Tuch, U.S. Patent No. 5,820,917, the 917-patent. That subject matter is encompassed by claim 64 and following.

Tuch does not teach or suggest that the "at least one second hemocompatible coating comprises one or more therapeutic heparin-containing compounds releasable into blood and an adhesion enhancer".

Since Tuch does not teach or suggest each and every element of claim 64, Tuch does not anticipate it. Claims 65-77 depend from claim 64 and contain all of the limitations of claim 64. Therefore, Tuch likewise fails to anticipate claims 65-77.

Previously, in the Office Action mailed 11 March 2002, paragraph 6, the Examiner rejected the subject matter of claims 60 (old claim 37) and 48 under 35 U.S.C. § 102(b) as being anticipated by Rowland et al., U.S. Patent No. 5,356,433 — the 433-patent.

As stated above claim 60 recites that (1) the coating increase biocompatibility and hemocompatibility of the blood-contacting surface and (2) the coating be adapted to deliver therapeutic amounts of therapeutic drugs into the blood wherein therapeutic drugs include heparin or heparin derivatives. Therefore, claim 48, since it depends from claim 60, also contains these limitations. The 433-patent does not teach or suggest these two limitations.

Since Rowland does not teach or suggest each and every element of claims 60 and 48, Rowland does not anticipate these claims. Since all of the claims that depend from claim 60 encompass all of the limitations of claim 60, Rowland likewise fails to

anticipate the dependent claims. Therefore, please remove this rejection under35 U.S.C. § 102(b).

Previously, in the Office Action mailed 11 March 2002, paragraph 7, the Examiner rejected the subject matter of claims 60 (old claim 37) and 62 (old claim 49) under 35 U.S.C. § 102(e) as being anticipated by Shah et al., U.S. Patent No. 6,240,127 — the 127-patent.

Shah does not teach or suggest the limitation that the coating is adapted to deliver therapeutic drugs into the blood. Shah is interested in a durable coating in which a biopolymer is covalently linked to a substrate. 127-patent, column 3, lines 1-5 and 49. Shah defines a biopolymer as including a group of heparin complexes: an ionic heparin complex is a biopolymer according to Shah. Shah covalently links this biopolymer to a substrate. 127-patent, column 2, line 48. "Covalent linkage of heparin molecules to a surface is understood to affect at least one, but not all, of the hydroxyl and amino moieties comprised by that molecule." 127-patent, column 4, lines 3-6. From this, one of ordinary skill in the art recognizes that Shah is after at least one covalent linkage between the substrate and each heparin molecule. Thus, Shah ensures that the heparin molecules are tied down on the surface of the substrate. Moreover, Shah teaches that coulombic (ionic) interactions are unsuitable for preparing a durable heparin coating. 127-patent, column 1, lines 58 and 66. Shah is interested in immobilizing heparin on the surface of a medical device, not in delivering therapeutic amounts of drugs using that device.

Since Shah does not teach or suggest each and every element of claims 60 and 62, Shah does not anticipate those claims. Since all of the claims that depend from claims 60 and 62 encompass all of the limitations of claims 60 and 62, Shah likewise fails to anticipate those dependent claims.

Previously, in the Office Action mailed 11 March 2002, paragraph 8, the Examiner rejected the subject matter of claims 60 (old claim 37) and 62 (old claim 49) under 35 U.S.C. § 102(e) as being anticipated by Ding et al., U.S. Patent No. 6,316,018 — the 018-patent.

Ding teaches a reservoir layer to deliver therapeutic drugs in the blood. Ding also teaches an outer layer that increases the biocompatibility and hemocompatibility of the blood-contacting surface. Ding does not teach or suggest a single coating combining both limitations as recited in claims 60 and 62. If Ding's reservoir layer is used alone, the biocompatibility and hemocompatibility of Ding's blood-contacting surface quickly washes away. Therefore, Ding's reservoir layer cannot be said to increase biocompatibility and hemocompatibility. If Ding's outer layer is used alone, it cannot be said that it delivers therapeutic amounts of therapeutic drugs into the blood.

Since Ding does not teach or suggest each and every element of claims 60 and 62, Ding does not anticipate these claims. Since all of the claims that depend from claims 60 and 62 encompass all of the limitations of claims 60 and 62, Ding likewise fails to anticipate the dependent claims.

35 U.S.C. § 103 claim Rejections

Previously, in the Office Action mailed 18 July 2001, paragraph 12, the Examiner rejected the subject matter of claims 81 (old claim 18) and 85 (old claim 22) under 35 USC 103(a), as being unpatentable over Zhong et al., U.S. Patent No. 6,197,051—the 051-patent in view of Hostettler et al., the 960-patent.

The 051-patent combined with the 960-patent does not teach or suggest a formulation wherein the formulation is adapted to deliver therapeutic amounts of heparin-containing compounds into the blood. Therefore, they do not teach and suggest each and every element of claims 81 or 85.

Since this combination does not teach or suggest each and every element of these claims, it does not make these claims obvious. Nor does it make obvious the claims that depend from claims 81 and 85.

Previously, in the Office Action mailed 18 July 2001, paragraph 13, the Examiner rejected the subject matter of claims 78 (old claim 15) and 85 (old claim 22) under 35

USC 103(a), as being unpatentable over Fox, Jr. et al., U.S. Patent No. 5,019,096—the 096-patent.

The 096-patent does not teach or suggest a formulation wherein the formulation is adapted to deliver therapeutic amounts of heparin-containing compounds into the blood. Therefore, it does not teach or suggest each and every element of claims 78 or 85. Since the 096-patent does not teach or suggest each and every element of these claims, it does not make these claims obvious. Nor does it make obvious the claims that depend from claims 78 and 85.

Previously, in the Office Action mailed 18 July 2001, paragraphs 14 and 15, the Examiner has rejected the subject matter of claims 64-68 (old claims 1-5) under 35 U.S.C. § 103(a) as being unpatentable over Hostettler, U.S. Patent No. 6,030,656, the 656-patent, and the Examiner has rejected the subject matter of claims 69-74 (old claims 6-11) under 35 U.S.C. § 103(a) as being unpatentable over Hostettler, the 656-patent, in view of Nygren et al.

Applicants have thoroughly searched the 656-patent including electronically searching the text version of the patent available from the Patent and Trademark Office's web site. As far as they can tell, Hostettler does not mention polysaccharides in conjunction with its polyurethane coating even once within the patent. The Examiner's help in specifically pointing out where in the specification such a teaching can be found would be greatly appreciated. Moreover, Hostettler does not teach adding any other therapeutic substance into its polymer coating. Therefore, it is Applicants' position that Hostettler does not teach or suggest that the "at least one second hemocompatible coating comprises one or more therapeutic heparin-containing compounds releasable into blood and an adhesion enhancer". Nygren does not supply this limitation, so even if properly combinable with Hostettler, the combination does not teach or suggest all the limitations of claim 64.

Since Hostettler does not teach or suggest each and every element of claim 64, Hostettler does not make it obvious. Claims 65-74 depend from claim 64 and contain all

of the limitations of claim 64. Therefore, Hostettler likewise fails to make claims 65-74 obvious.

Previously, in the Office Action mailed 11 March 2002, paragraphs 14, 15, 16, and 17, the Examiner rejected the subject matter of claims 60 (old claim 37) and 62 (old claim 49) under 35 U.S.C. § 103(a) as being obvious in view of a prior art combination based on Zhong, U.S. Patent No. 6,197,051; a prior art combination based on Hostettler et al., U.S. Patent No. 6,030,656; and a prior art combination based on Onishi et al., U.S. Patent No. 5,670,558.

None of these combinations contain the limitation that the coating "is adapted to deliver therapeutic amounts of therapeutic drugs into the blood" as do claims 60 and 62. Each is concerned with permanently affixing a coating to a substrate, not delivering drugs from the coating. When the references do teach a therapeutic drug, the drug is covalently bound to the substrate. When the drug is covalently bound, it is not deliverable in therapeutic amounts.

Since these combinations do not teach or suggest each and every element of claims 60 and 62, they do not make these claims obvious. Since all of the claims that depend from claims 60 and 62 encompass all of the limitations of claims 60 and 62, the combinations likewise fail to make the dependent claims obvious.

Since all claims are in a condition for allowance, please issue a Notice of Allowability so stating. If I can be of any help, please contact me.

Respectfully submitted,

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